JUN 2 8 1999

K991061

510(k) [redacted], Dermaphylyx Calcium Alginate Wound Dressing
Dermaphylyx, Inc.

510(k) Summary

Proprietary Name: Dermaphylyx Calcium Alginate Wound Dressing

Common Name: Dressing

Classification: Unclassified

Submitter's Details: Dermaphylyx, Inc.
78-E, Olympia Avenue,
Woburn, MA 01801-2057
Tel: (781) 933-4772
Fax: (781) 933-3933

Description:

Dermaphylyx Calcium Alginate Wound Dressings consist of calcium alginate fibers fabricated into felt and rope configurations.

Dermaphylyx Calcium Alginate Wound Dressings are engineered to absorb substantial quantities of wound exudate. During the absorption of exudate the dressing forms a gel/fiber mat. The formation of the gel/fiber mat may help facilitate removal from the wound.

Dermaphylyx Calcium Alginate Wound Dressings are intended for use in the management of partial and full- thickness wounds in both a professional and OTC environment. They may be used on the following wounds:

Venous ulcers	Superficial burns
Diabetic ulcers	Abrasions and lacerations
Pressure ulcers	Donor sites
Arterial ulcers	Postoperative wounds

Dermaphylyx Calcium Alginate Wound Dressings may also be used to control minor bleeding.

Over the Counter applications include abrasions, minor cuts, minor lacerations, as well as minor burns and the control of minor bleeding.

Dermaphylyx Calcium Alginate Wound Dressings are substantially equivalent to Innovative Technologies Calcium AlginateWound Dressings (Innovative Technologies Group, Ltd.) and Kaltostat® Calcium Alginate Wound Dressings (Calgon Vestal Laboratories). These devices are absorptive Calcium Alginate Wound Dressings, manufactured from calcium alginate fibers. They are intended for use in the management of a wide variety of wounds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 1999

Andrew M. Reed, Ph.D.
Principal
Dermaphylyx, Inc.
78-E Olympia Avenue
Woburn, Massachusetts 01801

Re: K991061
Trade Name: Calcium Alginate Wound Dressing
Regulatory Class: Unclassified
Product Code: MGQ
Dated: March 26, 1999
Received: March 30, 1999

Dear Dr. Reed:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K991061

510(k) Dermaphylyx Calcium Alginate Wound Dressing
Dermaphylyx, Inc.

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510(k) Number: K 991061
Dermaphylyx, Inc.

Device Name: Dermaphylyx Calcium Alginate Wound Dressing

Indications for Use:

Dermaphylyx Calcium Alginate Wound Dressings are intended for use in the management of a variety of partial and full-thickness wounds. The dressings are additionally intended to help control minor bleeding.

The following Indications are for Prescription Use or under the direction of a health care professional:

Venous ulcers	Superficial burns
Diabetic ulcers	Abrasions and lacerations
Pressure ulcers	Donor sites
Arterial ulcers	Postoperative wounds

The following Indications are for Over-the-Counter Use:

Abrasions
Minor Burns
Minor Cuts
Minor Lacerations

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

~~OR~~ AND

Over-The-Counter Use X

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Restorative Devices
510(k) Number K991061